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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/811,293	03/26/2004	Andy H. Levine	2814.2008-001	8260

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EXAMINER	
MILLER, CHERYL L	
ART UNIT	**PAPER NUMBER**
3738	

MAIL DATE	DELIVERY MODE
09/14/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/811,293	LEVINE ET AL.	
	Examiner	Art Unit	
	Cheryl Miller	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 July 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-49* is/are pending in the application.

4a) Of the above claim(s) *21-48* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20 and 49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/18/07, 7/18/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claims 1-20 have been considered but are moot in view of the new ground(s) of rejection.

Applicant's arguments with respect to claim 49 is non-persuasive. The applicant has argued that Kagan does not disclose a planar membrane that has dimensions of 7-20 cm. These limitations are not claimed in claim 49. See rejection below.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "the restrictive membrane" twice in 7. There is insufficient antecedent basis for this limitation in the claim. The limitation is previously recited as a restrictive member. Claims 2-20 depend upon claim 1 and inherit all problems associated with the claim.

Claim 19 recites the limitation "the restrictive membrane" in line 3. There is insufficient antecedent basis for this limitation in the claim.

Claims 14-16 are also rendered indefinite since the "clip retaining device comprising a retaining ring" is not part of the gastrointestinal implant, but instead part of the implantation tool.

The combination therefore is being claimed, however is not under the scope of the preamble which calls for a gastrointestinal implant only.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 49 is rejected under 35 U.S.C. 102(e) as being anticipated by Kagan et al. (US 2005/0240279 A1, cited previously). Kagan discloses an implant (fig.2a, 2b) comprising a restrictive member/means (stoma 100) and an anchor/anchor means (separate anchoring structure 108 seen in fig.2a) removably coupled to the restrictive member (P0139), wherein the restrictive member (100) comprises a membrane having an aperture (110, 152).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-10, 12, 13, 14, and 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Khosravi (US 5,925,063). Referring to claims 1-4, Khosravi discloses a gastrointestinal implant (fig.4B; col.6, lines 51-55) comprising a substantially planar restrictive

member (28) having an interior aperture (33) and an anchor (stent 21) *configured* to couple to the stomach (col.6, lines 51-55) and removably couple to the restrictive member (is considered remov*able*, may tear away adhesive) the anchor (stent 21) having an exterior perimeter adapted to contact the stomach (fig.4B). Khosravi discloses the implant for placement in the stomach substantially as claimed (col.6, lines 51-55), however does not disclose the size (width) of the restrictive member and of the aperture. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the width claimed (7-20 cm) since such a modification would have involved a mere change in the size of a component, and since Khosravi's implant is being placed in the same location as the applicants thus need to be the same size to fit in such a location. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 (USPQ 237 (CCPA).

Referring to the remaining dependent claims, Khosravi discloses the restrictive member to be made of the materials claimed (col.4, lines 57-60; col.5, lines 1-5). Khosravi discloses the restrictive member (28) to have a feature (29 or adhesive, col.4, lines 36-39) for coupling to the anchor (21). Khosravi discloses the anchor (21) to have a plurality of clips (24, see fig.2, 6C). Khosravi discloses the anchor to be NiTi (col.4, lines 8-12). Khosravi discloses the anchor (21) to have a feature (adhesive, col.4, lines 36-39) for coupling to the restrictive member (28).

Claims 11 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Khosravi (US 5,925,063) in view of Saadat (US 7,160,312 B2). Khosravi discloses a gastrointestinal implant (col.6, lines 51-55; fig.4B) substantially as claimed (see above). Khosravi discloses a restrictive member (28) coupled to an anchor (21), however uses adhesive

(col.4, lines 36-39) instead of hook and loop connections as claimed. Saadat teaches in the same field of gastrointestinal implants (abstract) the use of a hook and loop connection (205, see fig.21a, 21b) between a restrictive member (172) and anchor (176, 76) as an alternative to adhesive or other bondings (see figs.18, 19). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Khosravi's gastrointestinal implant with Saadat's teaching of an alternate attachment means for gastrointestinal implants, in order to provide an alternate attachment means to suit the needs of the patient (this one may be attached at the time of surgery).

Claims 1-14 and 17-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stack et al. (US 7,146,984 B2). Referring to claims 1-4, Stack discloses a gastrointestinal implant (col.2, lines 21-23; fig.5B) comprising a substantially planar restrictive member (42a) having an interior aperture (44a) and an anchor (40a OR 46a) *configured* to couple to the stomach (col.2, lines 21-23) and removably couple to the restrictive member (is considered remov*able*) the anchor (40a OR 46a) having an exterior perimeter adapted to contact the stomach. Stack discloses the implant for placement in the stomach substantially as claimed (col.2, lines 21-23), however does not disclose the size (width) of the restrictive member and of the aperture. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the width claimed (7-20 cm) since such a modification would have involved a mere change in the size of a component, and since Stack's implant is being placed in the same location as the applicants thus need to be the same size to fit in such a location. A

change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 (USPQ 237 (CCPA).

Referring to the remaining dependent claims, Stack discloses the restrictive member (42a) to be made of the materials claimed (col.7, lines 15-18; col.4, lines 1-30). Stack discloses the restrictive member (42a) to have a feature (screws, snaps, sutures, clips, staples an other fasteners; col.5 lines 60-col.6 line 15) for coupling to the anchor (46a or 40a) and vise versa. Stack discloses the anchor (40a OR 46a) to be NiTi (col.4, line 25).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl Miller whose telephone number is (571) 272-4755. The examiner can normally be reached on Monday-Friday 7:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4755. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Cheryl Miller

BRUCE SNOW
PRIMARY EXAMINER